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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,924	08/18/2006	Franz Xaver Schwarz	33660-US-PCT	1065

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EXAMINER	
AHMED, HASAN SYED	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
08/03/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,924	SCHWARZ, FRANZ XAVER	
	Examiner	Art Unit	
	HASAN S. AHMED	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/24/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's: amendment, remarks, and IDS, all filed on 24 May 2010.

* * * * *

Status of the Claims

Claims 1-35 have been cancelled. Claims 36-58 are newly submitted and are presently under prosecution.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 47 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Specifically, claim 47 claims the addition of water to the granulation liquid of claim 36 in an amount to compensate for the loss of crystallization water of the amoxicillin trihydrate caused by extrusion. However, the specification does not disclose the actual concentration of water in the granulation liquid that is required to compensate for the loss of crystallization water of the amoxicillin trihydrate caused by extrusion. As such, the specification does not reasonably convey to on skilled in the art

that the inventor had possession of the claimed invention at the time the application was filed.

*

2. Claims 48 and 49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Specifically, claim 48 claims the process of claim 36 wherein the granulate free of pharmaceutically acceptable excipients and claim 49 claims the process of claim 36 wherein the granulate is free of, *inter alia*, flavoring agents. Examiner respectfully submits that these claims contradict the claim from which they depend, i.e. claim 36, because claim 36 recites a granulate comprising micronized amoxicillin trihidrate and sugar. Sugar is routinely used in the pharmaceutical art as a pharmaceutically acceptable excipient (e.g. an inert core, a binder, or a filler) and as a flavoring agent (i.e. a sweetening agent). As such, the specification does not reasonably convey to on skilled in the art that the inventor had possession of the claimed invention at the time the application was filed.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 36, 38, 39, 41-46, 50, 53, 54, and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 080 862 ("Grimmett") (cited in the IDS filed on 18 August 2006).

Grimmett discloses water-dispersible extruded granules comprising amoxicillin trihydrate and sugar (see e.g. page 1, line 14; claim 1). The granules are prepared by, "...bringing into association the components [of the granule] and thereafter extruding the blended mixture." See page 3, lines 2-6. The amoxicillin trihydrate and sugar, *inter alia*, are passed through a screen (reading on claim 36) (see example 1). Disclosed granulation solvents include hygroscopic hydrophilic organic solvents such as methanol, ethanol, n- and iso-propanol (see page 2, lines 25-26). As currently amended, claim 36 claims a "granulation liquid comprising water". This limitation does not include a lower limit water concentration; as such, one molecule of water in the granulation liquid reads on claims 36 and 58 as currently constructed. Grimmett teaches that formulation of the disclosed composition can take place in an atmosphere of up to 40% relative humidity (see page 3, line 9). In an atmosphere of up to 40% relative humidity, hygroscopic hydrophilic organic solvents such as methanol, ethanol, n- and iso-propanol will inherently contain at least one molecule of water, reading on claim 36 as currently constructed. The extruded product is collected and passed through a screen and dried (reading on claim 36) (see example 1). The dried extrudate is then blended with 5% SYLOID (reading on the homogenization of claim 36) (see example 1). The granulate may be dissolved in water to form a syrup (reading on the smooth suspension of claim

36) (see page 3, lines 18-19). Sugar is the common word for sucrose, as such, the sugar disclosed by Grimmett is deemed to be functionally equivalent to the sucrose of instant claims 38, 39, and 44. Amoxycillin trihydrate concentration is disclosed as, e.g., 13.65% (reading on the ranges recited in instant claims 41-43) (see example 1). Sugar (sucrose) concentration is disclosed as, e.g., 68.9% (reading on the concentration recited in claim 44) (see example 1). The granulate particle size is disclosed as 1000 micrometers (reading on claims 45, 46, 53, and 54) (see example 1). The process disclosed by Grimmett does not involve grinding or micronizing (reading on claim 50).

*

2. Claim 51 rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 080 862 ("Grimmett") (cited in the IDS filed on 18 August 2006) as evidenced by U.S. Patent No. 7,157,094 ("Gaytan").

Grimmett discloses an extrusion step (see above). While Grimmett does not disclose an extrusion temperature, it is known in the art that temperatures in extruders operating at normal, commercial extrusion rates expose extruded material to temperatures of 25 to 100 degrees C (see Gaytan, col. 1, lines 38-40).

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claim 37 rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 080 862 ("Grimmett") in view of U.S. Patent No. 6,242,382 ("Bratz") further in view of U.S. Patent No. 4,177,254 ("Khan") (cited in the IDS filed on 18 August 2006).

Grimmett is discussed above. Grimmett differs from the instant application in that it does not teach a granulation liquid comprising sugar. However, use of a granulation liquid comprising sugars in extruder granulation techniques was known in the art at the time the instant application was filed as evinced by Bratz (see col. 14, lines 30-31). Bratz discloses sugars as binders in the granulation liquid (see col. 14, line 28). Khan explains that use of binders such as sucrose in a granulation liquid is beneficial because reconstitution of granules made with binders such as sucrose readily yields a suspension of the active ingredient (see col. 2, lines 48-57).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use sugar in a granulation liquid, as taught by Grimmett in view of Bratz, further in view of Khan. One of ordinary skill in the art at the time the invention was made would have been motivated to use a sugar in a granulation liquid because reconstitution of granules made with binders such as sucrose readily yields a suspension of the active ingredient, as explained by Khan (see above).

*

2. Claims 40 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 080 862 ("Grimmett") in view of U.S. 2002/0006433 ("Davidson") (cited in the IDS filed on 18 August 2006).

Grimmett is discussed above. Grimmett explains that the disclosed composition is beneficial the treatment of bacterial infections (see page 1, line 3). Grimmett differs from the instant application in that it does not teach the sugar alcohol of instant claim 40 or the homogenization conducted in a tumbler mixer of instant claim 52. Regarding claim 40, granulate compositions comprising amoxicillin trihydrate and mannitol were known in the art at the time the instant application was filed, as evinced by Davidson (see, e.g., p. [0021]). Davidson explains that mannitol is beneficial as a chewable base (see, e.g., p. [0006]).

Regarding claim 52, the process of blending the dried extrudate with 5% SYLOID is deemed to be functionally equivalent to the homogenization conducted in a tumbler mixer, since both processes will result in mixing of a sieved extrudate, which in turn will result in homogenization of the dried, sieved, extruded mass.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a method of making a granulate comprising amoxicillin trihydrate and mannitol, as taught by Grimmett in view of Davidson. One of ordinary skill in the art at the time the invention was made would have been motivated to use mannitol because it is beneficial as a chewable base, as explained by Davidson (see above).

*

3. Claims 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 080 862 ("Grimmett") in view of WO 03/063820 ("Schwarz") (cited in the IDS filed on 18 August 2006).

Grimmett is discussed above. Grimmett differs from the instant application in that it does not teach the particle sizes recited in claims 55-57. Schwarz teaches granulation of a beta-lactam antibiotic wherein the granulation liquid may be an organic solvent mixed with water (see page 5, lines 6-19). The granulation mass is then extruded (see page 5, line 28) and sieved (see page 5, line 33). Disclosed beta-lactam antibiotics include amoxicillin trihydrate (see page 3, lines 9-10). One disclosed average grain size is 30 micrometers (see page 10, line 20), reading on the particle size ranges recited in claims 55-57. Schwarz explains that the disclosed particle size is beneficial for the production of a granulate that is stable to segregation (see page 10, line 19).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have a granulate comprising particles of amoxicillin sized between 0.1 micrometers to 100 micrometers, as taught by Grimmett in view of Schwarz. One of ordinary skill in the art at the time the invention was made would have been motivated to use said particle size in a granulate because it produces a granulate that is stable to segregation, as explained by Schwarz (see above).

* * * * *

Response to Arguments

Applicant's arguments filed on 24 May 2010 have been fully considered but they are not persuasive. Applicant's main argument is that the granulation liquids disclosed by Grimmett do not contain water. However, as explained in the 35 USC 102(b) rejection, above, newly presented claim 36 claims a “granulation liquid comprising

water". This limitation does not include a lower limit water concentration; as such, one molecule of water in the granulation liquid reads on claims 36 and 58 as currently constructed. Grimmett teaches that formulation of the disclosed composition can take place in an atmosphere of up to 40% relative humidity (see page 3, line 9). In an atmosphere of up to 40% relative humidity, hygroscopic hydrophilic organic solvents such as methanol, ethanol, n- and iso-propanol will inherently contain at least one molecule of water, reading on claim 36 as currently constructed.

Other arguments presented by applicant are moot in view of applicant's newly submitted claims and the new grounds of rejection in view of the new limitations presented in the new claims.

* * * * *

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615